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SENATE BILL 2141

By Reeves

AN ACT to amend Tennessee Code Annotated, Title 56; Title 63 and Title 68, relative to drug donation repository program.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 10, Part 5, is amended by deleting the part and substituting:

63-10-501. Part definitions.

As used in this part:

(1) "Anti-rejection drug" means a prescription drug that suppresses the immune system to prevent or reverse rejection of a transplanted organ;

(2) "Board" means the board of pharmacy;

(3) "Cancer drug" means a prescription drug that is used to treat:

(A) Cancer or the side effects of cancer; or

(B) The side effects of a prescription drug that is used to treat cancer or the side effects of cancer;

(4) "Controlled substance" has the same meaning as defined in § 39-17-402;

(5) "Department" means the department of health;

(6) "Donor" means:

(A) A person, including an individual member of the public and an entity legally authorized to possess medicine in the state in which it is located with a license or permit in good standing;

(B) A pharmacy or medical facility; or

(C) A drug manufacturer or wholesaler;

(7) "Eligible patient" means:

(A) An indigent, uninsured, or underinsured patient; or

(B) If an indigent, uninsured, or underinsured patient is unavailable, another person in need of donated prescriptions or supplies;

(8) "Eligible recipient" means a nonprofit, for-profit, or federally owned medical facility or pharmacy that voluntarily participates in the program established by this part;

(9) "Indigent" means an individual with an income that is below six hundred percent (600%) of the federal poverty level as defined by the most recently revised poverty income guidelines published by the United States department of health and human services;

(10) "Medical facility" means:

(A) A physician's office;

(B) A hospital as defined in § 68-11-201;

(C) A health clinic;

(D) A nonprofit health clinic, including a federally-qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B); a rural health clinic as defined in 42 U.S.C. § 1396d(l)(1); and a nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured;

(E) A free clinic as defined in § 63-6-703;

(F) A charitable organization as defined in § 48-101-501; or

(G) A nursing home as defined in § 68-11-201;

(11) "Pharmacy" means a pharmacy as defined in § 63-10-204;

(12) "Prescription drug":

(A) Has the same meaning as defined in § 63-10-204;

(B) Includes, but is not limited to, tablets, capsules, inhalers, patches, injectables, and solutions, and includes cancer drugs and anti-rejection drugs; and

(C) Does not include controlled substances; and

(13) "Supplies" means the supplies necessary to administer the prescription drugs donated pursuant to this part.

63-10-502. Prescription drug donation repository program.

(a) The board of pharmacy, in cooperation with the department of health, may establish and maintain a prescription drug donation repository program under which a person may donate prescription drugs and supplies for use by an individual who meets eligibility criteria. The board may contract with a third party to implement and administer the program.

(b) A pharmacy or medical facility may elect to participate in the prescription donation program by providing, on a form prescribed by the department and available on the program's webpage, written notification to the department of the following:

(1) The name, street address, and telephone number of the pharmacy or medical facility, and a state issued license or registration number issued to the pharmacy or medical facility, including the name of the issuing agency;

(2) The name and telephone number of the responsible pharmacist, physician, physician's assistant, or nurse practitioner who is employed by or under contract with the pharmacy or medical facility; and

(3) A statement, signed and dated by the responsible pharmacist, physician, physician's assistant, or nurse practitioner, indicating that the

pharmacy or medical facility meets the eligibility requirements and shall comply with the program.

(c)

(1) Except as provided in subsection (d), the drugs must be in their original sealed and tamper-evident unit dose packaging. The packaging must be unopened. However, the drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed.

(2) The repository program shall develop and implement standards and procedures to determine, based on a basic visual inspection, that the drugs appear to be unadulterated, safe, and suitable for dispensing.

(d) High value specialty medications, including, but not limited to, cancer drugs, that are not in original sealed and tamper-evident unit dose packaging may be donated to a drug repository program.

(e) Donations of prescription drugs and supplies under the program may be made on the premises of an eligible recipient, or via mail to an eligible recipient, that elects to participate in the program and meets the requirements established by the board.

(f) An eligible recipient may receive, accept, replenish, repackage, and store donated prescriptions and supplies in accordance with the rules of the program.

(g) Donation and facilitation of a donation are not considered wholesale distribution, and a person donating or facilitating a donation does not require licensure as a wholesaler.

(h) Eligible recipients shall prioritize dispensing of donated prescriptions and supplies as follows:

(1) First, to an indigent patient;

(2) Second, to a patient who has no prescription drug insurance or cannot afford the out-of-pocket expenses for the drug prescribed; and

(3) Lastly, to another individual if an indigent, uninsured, or underinsured patient is unavailable.

(i) An eligible recipient shall not charge or collect fees from an eligible patient for prescriptions or supplies dispensed pursuant to the program. However, an eligible recipient may charge a handling fee for each donated drug or supply that is dispensed.

(j) An eligible recipient may charge fees, including, but not limited to, a usual and customary charge, to donors, eligible recipients, health plans, pharmacy benefit managers, and other entities. The fee must not exceed the reasonable cost of educating and providing technical support to donors and patients, shipping and handling, labor, storage, licensing, insurance, utilities, advertising, technology, supplies, and equipment.

(k) A medical facility or pharmacy that receives prescription drugs or supplies may distribute the prescription drugs or supplies to another eligible recipient for use pursuant to the program or to similar reclamation programs in other states.

(l) Participation in the program is voluntary.

63-10-503. Acceptance and dispensing of donated prescription drugs and supplies.

(a) A prescription drug or supplies may be accepted and dispensed under the prescription drug donation repository program if the following are met:

(1) A licensed pharmacist employed or under contract with the program inspects donations to determine if the donations are suitable for dispensing. The pharmacist shall sign an inspection record stating that, to the extent reasonably

possible in the judgment of the pharmacist, the drugs or supplies are not adulterated or misbranded, and are safe and suitable for dispensing;

(2) Eligible recipients store inventory in a secure area under environmentally appropriate conditions;

(3) Eligible recipients redact donor information from the packaging;

(4) Donated inventory is physically or electronically separated from non-donated inventory;

(5) Eligible recipients quarantine all eligible donations from dispensing stock until the donations have been inspected and approved for dispensing under the program, returned, or destroyed;

(6) Donated inventory may be used to replenish purchased inventory in compliance with applicable provisions of 42 U.S.C. § 256b and regulations promulgated pursuant to that statute;

(7) Donated inventory may be repackaged. Repacked drugs must be labeled with drug name, strength, and expiration date;

(8) Eligible recipients maintain an electronic inventory that includes drug name, national drug code number, quantity, expiration date, and date of donation;

(9) An identifier or bar code may be used in place of information required by law for a record or label if the identifier or bar code allows for that information to be readily retrievable;

(10) Eligible recipients return or destroy donated drugs or supplies that are not suitable for dispensing and make a record of the return or destruction that includes drug name, strength, quantity, method of destruction, and date of destruction;

(11) Eligible recipients dispose of donated prescriptions and supplies by returning the donated prescriptions and supplies to the donor, transferring the donated prescriptions and supplies to a reverse distributor, or incinerating the donated prescriptions and supplies in an incinerator that is approved by the federal environmental protection agency;

(12) The record of transaction history for a drug is maintained, beginning with the donor of the drug, including all prior donations, but not including information that is not required by law to be placed on the drug's label;

(13) Eligible recipients dispense in compliance with all applicable federal and state laws and regulations for dispensing, labeling, packaging, record keeping, drug utilization review, and patient counseling. A drug or supply must not be dispensed after its expiration date;

(14) An expiration date is required on all dispensed drugs. The expiration date must be brought forward to the filled prescription. If multiple packaged donated drugs are used to fill a single prescription with varied expiration dates, then the shortest expiration date must be used for the dispensed prescription;

(15) Dispensed drugs must not expire before the end use date by patient based on prescriber's directions;

(16) Controlled substances are not accepted for donation. Controlled substances must be disposed of pursuant to regulations promulgated by the federal drug enforcement administration (DEA). Destruction is accomplished by the use of a reverse distributor or following current regulations promulgated by the federal drug enforcement administration (DEA) regarding destruction of controlled substances; and

(17) Prescription drugs that are part of a risk evaluation and mitigation strategy program of the federal food and drug administration must not be accepted for donation.

(b)

(1) If a person who donates prescription drugs under this part to a medical facility or pharmacy receives a notice from a pharmacy that a prescription drug has been recalled, then the person must inform the medical facility or pharmacy of the recall.

(2) If a medical facility or pharmacy receives a recall notification from a person who donated prescription drugs under this part, then the medical facility or pharmacy must perform a uniform destruction of all of the recalled prescription drugs in the medical facility or pharmacy.

(c) The board shall adopt rules establishing the following:

(1) Requirements for medical facilities and pharmacies to accept and dispense donated prescription drugs and supplies, including the following:

(A) Eligibility criteria for participation by medical facilities and pharmacies;

(B) Standards and procedures for accepting, safely storing, and dispensing donated prescription drugs and supplies;

(C) Standards and procedures for inspecting donated prescription drugs to determine if the prescription drugs are in their original sealed and tamper-evident packaging, or if the prescription drugs are in single-unit doses or blister packs and the outside packaging is opened, if the single-unit dose packaging remains intact; and

(D) Standards and procedures for inspecting donated prescription drugs and supplies to determine that the prescription drugs and supplies are not adulterated or misbranded;

(2) Eligibility criteria for individuals to receive donated prescription drugs and supplies dispensed under the program. The standards must prioritize dispensing to individuals who are indigent or uninsured, but may permit dispensing to other individuals if an uninsured or indigent individual is unavailable;

(3) Necessary forms for administration of the prescription drug donation repository program, including forms for use by individuals who donate, accept, distribute, or dispense the prescription drugs or supplies under the program. However, the board may also approve the use of forms created by eligible recipients;

(4) A means by which an individual who is eligible to receive donated prescription drugs and supplies may indicate eligibility; and

(5) A list of prescription drugs that the prescription drug donation repository program will accept.

63-10-504. Immunity and exemption.

(a) A drug manufacturer acting reasonably and in good faith, is not subject to criminal prosecution or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the drug manufacturer that is donated under this part, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

(b) Except as provided in subsection (c), a person other than a drug manufacturer subject to subsection (a), acting reasonably and in good faith, is immune from civil liability and criminal prosecution for injury to or the death of an individual to whom a donated prescription drug is dispensed under this part and is exempt from disciplinary action related to the person's acts or omissions related to the donation, acceptance, distribution, or dispensing of a donated prescription drug under this part.

(c) The immunity and exemption provided in subsection (b) does not extend to the following:

(1) The donation, acceptance, distribution, or dispensing of a donated prescription drug under this part by a person if the person's acts or omissions are not performed reasonably and in good faith; or

(2) Acts or omissions outside the scope of the program.

63-10-505. No restriction on use of samples.

This part does not restrict the use of samples by a physician or other person legally authorized to prescribe drugs pursuant to this title during the course of the physician's or other person's duties at a medical facility or pharmacy.

63-10-506. Resale of prescription drugs not authorized.

This part does not authorize a person to resell prescription drugs.

63-10-507. Promulgation of rules.

The board of pharmacy is authorized to promulgate rules to effectuate this part. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 2. If a provision of this act or its application to a person or circumstance is held invalid, then the invalidity does not affect other provisions or applications of the act that can

be given effect without the invalid provision or application, and to that end the provisions of this act are severable.

SECTION 3. The headings in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 4. For the purpose of rule promulgation, this act takes effect upon becoming a law, the public welfare requiring it. For all other purposes, this act takes effect January 1, 2023, the public welfare requiring it.